



PATENT
Customer No. 22,852
Attorney Docket No. 6832.0064

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Craig A. Rosen et al.)	Group Art Unit: 1653
)	
Application No.: 10/775,180)	Examiner: Karen C. Carlson, Ph.D.
)	
Filed: February 11, 2004)	
)	
For: ALBUMIN FUSION PROTEINS)	Confirmation No.: 1800

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TO REQUIREMENT FOR INFORMATION UNDER 37 C.F.R. § 1.105

The Office mailed a communication dated March 1, 2006, in which the Office asserted that the Response to Restriction Requirement filed by Applicants on December 15, 2005, was not fully responsive because Applicants have not elected a single sequence for search. The Office did not set a new period for reply, but instead, indicated that the period for reply and period of extension by payment of fees is the same as those set forth in the prior Office Action (dated October 3, 2005). Applicants have concurrently submitted a paper addressing the Restriction Requirement.

In that same communication dated March 1, 2006, the Office also required Applicants, under Rule 1.105, to state which references of the 896 references submitted are "specifically relevant to the claimed invention." The Office did not set forth a period for reply to the Rule 1.105 requirement for information but indicated that Applicants

must provide the requested information “[o]nce Applicants have elected their invention.” No Office Action on the merits has yet been issued in the instant application. According to MPEP § 704.13, “[r]equirements for information under 37 CFR 1.105 made without an action on the merits should set a shortened statutory period of two months for reply. Applicant may extend the time period for reply up to six months in accordance with 37 CFR 1.136(a).” (Emphasis original) However, because the Rule 1.105 requirement did not identify a period for reply, Applicants submit that the current reply is timely filed within the six month statutory period, and no extension of time fee is required. See MPEP § 710.

Applicants respectfully assert that it is unclear what the Office considers “specifically relevant to the claimed invention.” Applicants submitted a list of references in the Information Disclosure Statements that Applicants considered relevant. However, to respond to the Rule 1.105 requirement, Applicants provide below the list of references that relate generally to albumin fusion protein technology and to GLP-1 polypeptides. In addition, Applicants have submitted concurrently with this response, a Supplemental Information Disclosure Statement which identifies additional related co-pending applications and other references that relate to albumin fusion protein technology and to GLP-1 polypeptides and their use in weight control. Those applications and references are also included in the list below.

U.S. Patent Document	Issue or Publication Date	Name of Patentee or Applicant of Cited Document
5,380,712	01/10/1995	Ballance et al.
5,545,618	08/13/1996	Buckley et al.
5,612,196	03/18/1997	Becquart et al.
5,646,012	07/08/1997	Fleer et al.
5,665,863	09/09/1997	Yeh et al.

U.S. Patent Document	Issue or Publication Date	Name of Patentee or Applicant of Cited Document
5,668,007	09/16/1997	Spencer et al.
5,766,883	06/16/1998	Ballance, et al.
5,876,969	03/02/1999	Fleer et al.
5,959,075	09/28/1999	Lok et al.
6,165,470	12/26/2000	Becquart et al.
6,191,102	02/20/2001	DiMarchi et al.
6,300,065	10/09/2001	Kieke et al.
6,514,500	02/04/2003	Bridon et al.
6,583,111	06/24/2003	DiMarchi et al.
6,686,179	02/03/2004	Fleer et al.
2005-0266533	12/01/2005	Balance et al.
2005-0266532	12/01/2005	Rosen et al.
2005-0244931	11/03/2005	Rosen et al.
2005-0186664	08/25/2004	Rosen et al.
2005-0100991	05/12/2005	Rosen et al.
2005-0048471	3/3/2005	Becquart et al.
2005-0037022	02/17/05	Rosen et al.
2004-0171123	09/02/2004	Rosen et al.
2004-0086977 (now U.S. Patent No. 6,987,006)	05/06/2004 (issued 1/17/2006)	Fleer et al.
2004-0086976 (now U.S. Patent No. 6,989,365)	05/06/2004 (issued 1/24/2006)	Fleer et al.
2004-0018975	01/29/2004	DiMarchi et al.
2004-0010134	01/15/2004	Rosen et al.
2003-0219875 (now U.S. Patent No. 6,905,688)	11/27/2003 (issued 6/14/2005)	Rosen et al.
2003-0199043	10/23/2003	Balance et al.
2003-0171267	09/11/2003	Rosen et al.
2003-0143191	7/31/2003	Bell et al.
2003-0125247 (now U.S. Patent No. 6,994,857)	07/03/2003 (issued 2/7/2006)	Rosen et al.
2003-0104578	6/5/2003	Balance
2003-0082747	5/1/2003	Fleer et al.
2003-0054554	3/20/2003	Becquart et al.
2003-0036172	2/20/2003	Fleer et al.
2003-0036171 (now U.S. Patent No. 6,972,322)	2/20/2003 (issued 12/6/2005)	Fleer et al.
2003-0036170	2/20/2003	Fleer et al.

U.S. Patent Document	Issue or Publication Date	Name of Patentee or Applicant of Cited Document
2003-0022308	1/30/2003	Fleer et al.
10/922,142 (now 2005-0054051)	(published 3/10/2005)	Rosen et al.
09/833,111 (now U.S. Patent No. 6,946,134)	(issued 9/20/2005)	Rosen et al.
10/933,523		Rosen et al.
11/175,690		Haseltine et al.
11/264,096		Rosen et al.
11/315,035		Balance
11/330,353		Fleer et al.
11/341,748		Rosen et al.

Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document
EP 0 624 195	11/17/1994	Rhone Poulenc Rorer SA
EP 0 946 191 B1	03/12/2003	Eli Lilly and Company
EP 1 306 092 A2	05/02/2003	Eli Lilly and Company
WO 98/19698	05/14/1998	Eli Lilly and Company
WO 01/77137	10/18/2001	Human Genome Sciences, Inc.
WO 02/46227	06/13/2002	Eli Lilly and Company
WO 03/059934	07/24/2003	Human Genome Sciences, Inc.
WO 03/060071	07/24/2003	Human Genome Sciences, Inc.
WO 05/000892	01/06/2005	Eli Lilly and Company
WO 05/003296	01/13/2005	Human Genome Sciences, Inc.
WO 05/077042	08/25/2005	Human Genome Sciences, Inc.

NON PATENT LITERATURE DOCUMENTS	
ADELHORST, K. et al., "Structure-Activity studies of glucagon-like peptide-1," J. Biol. Chem. 269 (9): 6275-6278 (1994).	
GALLWITZ, B. et al., "Structure/activity characterization of glucagon-like peptide-1," Eur. J. Biochem. 225: 1151-1156 (1994).	
HJORTH, S.A. et al., "Glucagon and glucagons-like peptide-1: selective receptor recognition via distinct peptide epitopes," J. Biol. Chem. 269 (48): 30121-30124 (1994).	
ORSKOV, C. et al., "Complete sequences of glucagons-like peptide-1 from human and pig small intestine," J. Biol. Chem. 264 (22): 12826-12829 (1989).	
PARKER, J.C. et al., "Structure-function analysis of a series of glucagons-like peptide-1 analogs," J. Peptide Res. 52: 398-409 (1998).	
URSO, B. et al., "Differences in signaling properties of the cytoplasmis domains of the insulin	

NON PATENT LITERATURE DOCUMENTS
receptor and insulin-like growth factor receptor in 3T3-L1 adipocytes," J. Biol. Chem. 274(43): 30864-30873 (1999).
YU, K. et al., "A newly identified member of tumor necrosis factor receptor superfamily (TR6) suppresses LIGHT-mediated apoptosis," J. Biological Chemistry, 274(2): 13733-13736 (1999)
European Search Report for Appln. No. 02799966.3-1212-US024891, Jan. 20, 2005
International Search Report for International App. No. PCT/US02/40891 (WO 2003/060071 A3) (April 21, 2003)
International Search Report for International App. No. PCT/US2002/040892 (WO 2003/059934 A3) (February 26, 2004)

This reply to the Rule 1.105 requirement does not represent that no better art exists or that a search has been made, and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." The above list is a non-exhaustive list of references which Applicants submitted in the Information Disclosure Statements. Applicants request that all of the references cited in the Information Disclosure Statements submitted to the Office be considered and not just the references listed above. Accordingly, Applicants request the Office to indicate that they were considered by making appropriate notations on the forms that were attached with the Information Disclosure Statements.

Although Applicants believe that no extension of time is required as discussed above, please grant any extensions of time if required to enter this response and charge any required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 31, 2006

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266



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Craig A. Rosen et al.) Group Art Unit: 1653
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For: ALBUMIN FUSION PROTEINS) Confirmation No.: 1800

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed U.S. patent documents are not enclosed but a copy of the listed foreign patent document is enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 31, 2006

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266

Complete if Known

**SUPPLEMENTAL INFORMATION
DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

1

Application Number

10/775,180

Filing Date

February 11, 2004

First Named Inventor

Craig A. Rosen et al.

Art Unit

1653

Examiner Name

Karen C. Carlson

Attorney Docket Number

6832.0064-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
		10/933,523	Pending (not published)	Rosen et al.	
		11/175,690	Pending (not published)	Haseltine et al.	
		11/264,096	Pending (not published)	Rosen et al.	
		11/315,035	Pending (not published)	Ballance	
		11/330,353	Pending (not published)	Fleer et al.	
		11/341,748	Pending (not published)	Rosen et al.	
		2003-0143191	07-31-2003	Bell et al.	
		2004-0018975	01-29-2004	DiMarchi et al.	
		2005-0048471	03-03-2005	Becquart et al.	
		2005-0100991	05-12-2005	Rosen et al.	
		2005-0244931	11-03-2005	Rosen et al.	
		2005-0266532	12-01-2005	Rosen et al.	
		2005-0266533	12-01-2005	Ballance et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Country Code Number Kind Code (if known)				
		EP 1 306 092 A2	05-02-2003	Eli Lilly & Company		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation

Examiner
SignatureDate
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.